



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0102]

Antiparasitic Drug Use and Resistance in Ruminants and Equines; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

The Food and Drug Administration (FDA) is announcing a public meeting entitled "Antiparasitic Drug Use and Resistance in Ruminants and Equines." The purpose of the meeting is to discuss the current state of anthelmintic resistance in the United States and worldwide, tools for the evaluation of antiparasitic resistance, evaluation of the effectiveness of drugs against resistant parasites, and the scientific rationale for the use of combinations of antiparasitic drugs in ruminants and equines.

Date and Time: The public meeting will be held on March 5 and 6, 2012, from 8 a.m. to 5:30 p.m.

Location: The meeting will be held at the Hilton Washington DC/Rockville Hotel & Executive Meeting Center, 1750 Rockville Pike; Rockville, MD 20852-1699; 1-800-774-1500; FAX 301-468-0163; <http://rockvillehotel-px.rtrk.com/>.

Contact Person: Aleta Sindelar, Center for Veterinary Medicine (HFV-3), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9004, FAX: 240-276-9030, email: Aleta.Sindelar@fda.hhs.gov.

Requests for Oral Presentations and Registration: Interested persons may present data, information, or views, orally or in writing, on the topic of the discussion of the meeting. Written submissions may be made to the contact person on or before February 27, 2012. Oral presentations from the public during the open public comment period will be scheduled between approximately 2 p.m. and 3 p.m. on March 5, 2012, and 10:30 a.m. and 12 noon on March 6, 2012. Those desiring to make oral presentations should notify the contact person by February 20, 2012, and submit a brief statement of the general nature of information they wish to present and an indication of the approximate time requested to make their presentation. Time allotted for each presentation may be limited. The contact person will inform each speaker of their schedule prior to the meeting.

Registration is not required for this meeting; however, early arrival is recommended because seating may be limited. If you need special accommodations due to a disability, please contact Aleta Sindelar, (see Contact Person) at least 7 days in advance.

Comments: Regardless of attendance at the public meeting, interested persons may submit either electronic or written comments regarding this document. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. The docket will remain open for written or electronic comments for 60 days following the meeting.

SUPPLEMENTARY INFORMATION: The main purpose of the meeting is to explore and discuss ways in which antiparasitic drugs can be used, alone or in combination, to maximize antiparasitic drug efficacy and minimize parasitic resistance in ruminant and equine species.

Other topics for discussion include:

- (1) The current state of anthelmintic resistance in the United States and in other parts of the world;
- (2) The factors that have contributed to the development of anthelmintic resistance;
- (3) The role of refugia in the management of anthelmintic resistance;
- (4) The use of mathematical modeling as a tool for evaluating resistance;
- (5) The use of the fecal egg count reduction test in the detection and management of anthelmintic resistance; and
- (6) Ways to maximize the effectiveness of anthelmintics for today and the future.

Agenda: The meeting will allow for public comment and discussion on current challenges regarding the use of antiparasitic drugs in ruminants and equines. The agenda for the public meeting will be made available on the Agency's Web site at

<http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/default.htm>.

Transcripts: FDA will prepare a meeting transcript and make it available on the Agency's Web site (see Agenda) after the meeting. FDA anticipates that transcripts will be available approximately 30 business days after the meeting. The transcript will be available for public examination at the Division of Dockets Management (see Comments section of this document), between 9 a.m. and 4 p.m., Monday through Friday. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written

requests are to be sent to Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: February 7, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012-3221 Filed 02/10/2012 at 8:45 am; Publication Date: 02/13/2012]